

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: THE WAVE 3 CASES LISTED IN EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' DAUBERT MOTION TO
EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF DR. SHELBY THAMES**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, Dr. Shelby Thames, ("Dr. Thames"). This document applies to the following Wave 3 cases identified in Exhibit A attached to Plaintiffs' motion.

I. Notice of Adoption

Plaintiffs hereby adopt and incorporate by reference the *Daubert* motion filed against Dr. Thames for Ethicon Wave 2, Dkt. 2455 (motion), 2458 (memorandum in support). Plaintiffs respectfully request that the Court exclude Dr. Thames testimony, for the reasons expressed in the Wave 2 briefing.

II. Additional Arguments

In their Wave 2 *Daubert* briefing (which is adopted and incorporated in these Wave 3 cases), Plaintiffs moved to exclude several of Dr. Thames' opinions because they are unscientific and unreliable. In Wave 3, Dr. Thames submitted a report containing the same opinions that were described in Wave 2 along with a supplement describing an experiment he performed on a

piece of intentionally oxidized Prolene mesh.¹ The purported purpose of this experiment is to find out after the fact if the cleaning protocol he used on Plaintiffs' explanted meshes "removes oxidation products formed and/or residing on Prolene's surface."² But this supplement is unfinished, statistically unreliable, scientifically unsound and irrelevant—as such, any opinions garnered from it should be excluded from trial.

1. Dr. Thames' supplement to his Wave 3 expert report is unfinished, making it pointless for any jury to consider.

Dr. Thames' supplement describes an unfinished experiment he performed on one piece of a TVT Prolene-based mesh. First, the supplement describes how Dr. Thames oxidized a piece of mesh in its entirety by placing it in prolonged contact with ultraviolet light—to the point that it crumbled after handling.³ The supplement then describes that oxidized sample being put through the first 4 steps of his 23 step cleaning protocol.⁴

"The oxidized Prolene exemplar is currently being processed through the cleaning steps of Figure 1, and that data will be reported when complete. At this writing we have completed steps 1 through 4 and these data are reported herein. Our experience to date has shown these first 4 steps to be those during which the majority of the proteins are removed, and if there is Prolene oxidation these are the steps where oxidation would most likely be observed."⁵

The simple fact that Dr. Thames' experiment is unfinished is enough to have any opinions he may draw from it excluded at trial. Any opinions from his continued testing or experimentation that are new and are after his report was submitted cannot be considered part of his expert disclosure, and they must be excluded from trial.

2. Dr. Thames does not have any statistical significance in his supplement.

¹ Exhibit B, Thames Wave 3 Report; Exhibit C, Thames Supplemental Report.

² Ex C, Thames Supplemental Report at 9.

³ Ex C, Thames Supplemental Report at 11.

⁴ Ex C, Thames Supplemental Report at 11.

⁵ *Id.*

Furthermore, Dr. Thames' experiment only oxidized one piece of a Prolene mesh by ultraviolet light.⁶ He has supplied the lot number of this mesh in his supplement, but that lot number does not track the history of the Prolene monofilaments that are used to knit this mesh.⁷ Those monofilaments could have been extruded at any time—and how they were stored or treated before they were knit into a mesh or after Dr. Thames received the mesh in 2013 is also not described in his supplement.⁸ Moreover, as Dr. Thames states in his report “at least 5 tests are required for statistical validity.”⁹

Even if his experiment were finished—and it is not—he simply would not have enough information to generate any significance for his opinions. As this Court has explained, “[t]he small sample size and Drs. Mays and Gido’s failure to determine the statistical significance of their results call into the question the reliability of their methods. Although Daubert is a flexible inquiry, these facts weigh heavily against the reliability of their opinions.” *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 at 27 (S.D. W.V. Sept. 29, 2014). Dr. Thames’ unfinished experiment uses only a single piece of Prolene mesh—whatever opinions he can garner from this experiment cannot be said to have any significance to the women implanted with the Prolene-based meshes that are part of this litigation. As such, they must be excluded.

3. The experiment described in Dr. Thames’ supplement is scientifically unsound and irrelevant because it does not take what is happening inside the human body into account.

The experiment described in Dr. Thames’ supplement is scientifically unsound and it is not related in any way to how these meshes are actually oxidized inside the human body. Dr. Thames created the experiment described in his supplement to counter Plaintiffs’ complaints

⁶ *Id.*

⁷ *Id.* at 12.

⁸ *Id.*

⁹ Ex. B , Thames Wave 3 Report at 59.

about his abrasive cleaning protocol¹⁰—yet he ignores the concept of surface oxidation and made no attempt to replicate the actual environment where these meshes are being oxidized. This is in direct conflict with what peer reviewed literature described as early as 1998:

Because this [oxidative] cracking is confined to the outer skin, which is clearly distinguishable from the inner core structure, it is not surprising to observe that, during abrasive stresses, such as cleaning, there was a tendency for the cracked rings at the surface to flake off and separate from the underlying core material.¹¹

Indeed, instead of creating an experiment that would actually assess if his cleaning protocol was destroying surface oxidation, Dr. Thames intentionally oxidized a sample of TVT in its *entirety* by using ultraviolet light—to the point where the sample crumbled apart.¹² But the fact that the entire sample was oxidized means that even *if* his cleaning protocol is destroying and removing the surface of the mesh, whatever remains after cleaning is *always* going to register as being oxidized.

Dr. Thames' experiment here is not an after-the-fact control to determine if his cleaning protocol is destroying evidence of oxidation—it is a rigged game with an outcome that is predetermined by the fact that he oxidized the entire sample. No matter how much of the surface is removed—the results of his analysis will always show oxidized material.

This is in contrast to the fact that Dr. Thames could have performed an experiment that only oxidized the surface of the mesh and then put that through his cleaning protocol. Indeed, Ethicon's expert Dr. MacLean performed one such experiment on Prolene mesh using an in-vitro solution originally created in the 1990's that only oxidizes the surface of the mesh material.¹³ Had Dr. Thames used that same in-vitro protocol to oxidize only the surface of his sample, then

¹⁰ Ex. C, Thames Supplemental Report at 9.

¹¹ Exhibit D, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, *Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery*, ASAIO Journal, 44 (1998) 199-206.

¹² Ex. C, Thames Supplement Report at 11.

¹³ Exhibit E, MacLean Wave 1 Supplemental Report at 9-22.

his experiment may have some value here. As it stands, however, the experiment described in his supplement is only an exercise in futility.

Plaintiffs have never alleged—nor does the literature provide—that what Dr. Thames did by oxidizing the entire sample is representative of what happens to polypropylene in the human body. As such, the experiment discussed in Dr. Thames’ supplemental report, and any opinions he garnered from it, should be excluded. Moreover, his testing and analysis were unfinished when he submitted his report, there cannot be any statistical validity to his findings, his intentionally oxidizing the entire sample does not represent what is actually happening in the human body, and he created a rigged game with a predetermined outcome when he oxidized the entire sample.

Dated: September 19, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace